

K 073 475

MAR 10 2008

**Summary of Safety and Effectiveness****System Plus Impression Material**

1. **Date of Summary Preparation:** June 22, 2007
2. **Submitting Firm:** Continental Dental Laboratory
3. **Contact Person:** Jerry Doviack, CDT  
President  
Continental Dental Laboratory  
1873 Western Way  
Torrance, CA 90501  
T: (310) 618-8821  
F: (310) 618-1238
4. **Name of Medical Device**
  - Proprietary Name:** System Plus Impression Material
  - Common Name:** Dental Impression Material
  - Classification Name:** Impression Material
5. **Description of Medical Device:**

System Plus is an addition-reaction silicone impression material. This vinyl polysiloxane (VPS) impression material comes in two different viscosities intended to help reproduce the structure of a patient's teeth and gums in order to produce, crowns, bridges, implants, and other dental restorations.

**Physical Properties**

PROPERTY	MEDIUM BODY	LIGHT BODY
Consistency, ISO 4823	Medium Body, Type 2	Light Body, Type 3
Color	yellow	blue
Working Time (Including Mixing)	30 -60 seconds	30-60 seconds
Time in Mouth	three minutes	three minutes
Total Setting Time (Including Mixing)	four minutes	four minutes
Strain in Compression %	4.7%	4.7%
Shrinkage after 24hr	<0.1%	<0.1%
Shore A Hardness	45	45

6. **Intended Use**

This VPS impression material is intended to be placed on an impression tray and used to reproduce the structure of a patient's teeth and gums in order to produce crowns, bridges, implants and other dental restorations. This product is for professional use only by or on the order of a licensed dentist.

7. **Substantial Equivalence Determination**

Continental Dental Laboratory has determined that System Plus Impression Material is substantially equivalent to:

K052090, Splash! – Discus Dental, Inc.

**Predicate Similarities**

PRODUCT	COMPANY	ISO 4823	STRAIN IN COMPRESSION	SHRINKAGE	SHORE A HARDNESS
System Plus	Continental Dental Lab	Type 2-3	<5%	<.1%	45
Splash!	Discus Dental	Type 0-3	2.3-2.5%	<.1%	62-67

**Predicate Differences**

PRODUCT	COMPANY	WORKING TIME (INC MIXING)	TIME IN MOUTH	TOTAL SETTING TIME	SHORE A HARDNESS
System Plus	Continental Dental Lab	30-60 seconds	3 minutes	≤ 4 minutes	45
Splash!	Discus Dental	55-65 seconds	1 min 15 sec	2 min. 15 sec	62-67

8. **Safety & Effectiveness**

**Continental Dental Laboratories** acknowledges that when used as directed, there are no known harmful reactions or side effects on patients and/or dental personnel using vinyl polysiloxane impression materials.

The company will continue to conduct safety assessments based on further research and analysis to ensure compliance with safety and performance specifications recorded and published for this product.

END OF SECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kareen Chamberlain  
Marketing Director  
Continental Dental Laboratory  
1873 Western Way  
Torrance, California 90501

**MAR 10 2008**

Re: K073475  
Trade/Device Name: System plus Impression Material  
Regulation Number: 872.3660  
Regulation Name: Impression Material  
Regulatory Class: II  
Product Code: ELW  
Dated: December 6, 2007  
Received: December 18, 2007

Dear Ms. Chamberlain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

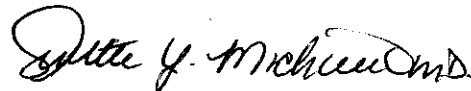
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K073475

Device Name: System Plus Impression Material

### Range of Indications:

System Plus is a vinyl polysiloxane dental impression material. It is ideal for one-step impressions to reproduce the structure of a patient's teeth and gums to produce crowns, bridges, inlays, partial and complete dentures, denture repairs, implants and other dental restorations prescribed by a dentist.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K073475